112 年度藥物開發及臨床試驗從業人員培訓班 歷史考題

1. Which of the following is **NOT** a part of the Investigational New Drug (IND) Review?
(A) Authorization to ship across the state lines
(B) Review of preclinical trial results
(C) Determination of safety in human use
(D) Identification of side effect profile

2. Which of the following statement concerning ICH GCP is correct?
(A) The manufacturing, processing, and storage of investigational new drug should follow GCP
(B) Investigational products should be used in accordance with the approved protocol
(C) Participants must submit informed consent forms after joining a clinical trial
(D) Foreseeable risks and inconveniences should be weighed against the anticipated benefit after clinical trials are initiated

3. GMP's are established and implemented to protect?
(A) Consumers
(B) The Plant Manager
(C) Company Reputation
(D) Quality Manager
(E) Both A and C

4. GMP applies to the lifecycle stages, from the:
(A) Technology transfer, commercial manufacturing through to product discontinuation.
(B) Commercial manufacturing through to product discontinuation.
(C) Manufacture of investigational medicinal products, technology transfer, commercial manufacturing through to product discontinuation.

5. Which technique is the **Less** common method used to protect the integrity of
(A) Randomization
(B) Placebo and control groups
(C) Double blinding
(D) Single blinding

6. Which two criteria does the FDA classify NDAs?
(A) Clinical improvement and effectiveness of the product
(B) The balance between safety and effectiveness
(C) The novelty of the active ingredient and clinical improvement
(D) The novelty of the active ingredient and time to market

7. Which one is **NOT** a reason promising compounds might be abandoned?
(A) Safety/toxicity issues
(B) Limited market potential
(C) Manufacturing difficulties
(D) Generic erosion

8. On average, it takes _____ years to do the discovery research and testing to bring a new drug to the market.
(A) 1-3
(B) 6-8
(C) 12-15
(D) over 20

9. Who is the person responsible for the conduct of the clinical trial at a trial site?
(A) Sponsor
(B) Monitor
(C)Investigator
(D) Clinical Research Coordinator (CRC)

10. What does ICH stand for?
(A) International Convention on Harmonisation
(B) International Conference on Harmonisation
(C) International Convention on Homogenization
(D) International Conference on Homogenization

11. Which of the following data are required for new drug application (NDA) but **NOT** for abbreviated new drug application (ANDA)?
(A) Phase I-III Clinical trial
(B) Quality control

(C) Bioavailability/Bioequivalence
(D) Chemistry, manufacturing and control (CMC)

12. Which phase of clinical trials includes healthy volunteers?
(A) Phase I
(B) Phase II
(C) Phase III
(D) Phase IV

13. Which of the following is responsible for issuing schedule 3 and 4 controlled drugs prescription licenses (三、四級管制藥品登記證)?
(A) Academia Sinica (中央研究院)
(B) Institute for Biotechnology and Medicine Industry (國家生技醫療產業策進會)
(C) Taiwan Food and Drug Administration (食品藥物管理署)
(D) Health Promotion Administration (國民健康署)

14. What must a pharmaceutical formulation contain?
(A) Active pharmaceutical ingredients (APIs) and assembler's name
(B) Active pharmaceutical ingredients (APIs) and excipients
(C) Wholesale dealer's address and assembler's name
(D) Expiration date of manufacturer's license

15. Which of the following types of drugs will have Maximum oral bioavailability?
(A) Drugs with high first-pass metabolism
(B) Highly hydrophilic drugs
(C) Chemically unstable drugs
(D) Largely hydrophobic, yet soluble in aqueous solutions

16. By how many years **in Maximum** can a drug patent be extended in Taiwan as of 2022?
(A) 5 years
(B) 10 years
(C) 15 years
(D) 20 years

17. Common Technical Document (CTD) is divided into how many modules?
(A) 3
(B) 4

(C) 5
(D) 6

18. Which of the following covid-19 vaccines utilizes viral vector as the base?
(A) Moderna
(B) AstraZeneca
(C) BioNTech (Pfizer)
(D) Medigen

19. Which of the following is **NOT** considered a biologic product?
(A) Biochip
(B) Blood
(C) Toxoid
(D) Vaccine

20. In a double-blind study within the context of a clinical trial, from whom is treatment allocation concealed?
A. Participant + Investigator
B. Participant + Monitor
C. Principal Investigator + Monitor
D. Participant + Investigator + Monitor